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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/047,985	01/17/2002	Nicholas R. Bachur JR.	P-5478	3233
7590 11/05/2003			EXAMINER	
David W. Highet		STOCK JR, GORDON J		
Becton Dickinson and Company Intellectual Property Department			ART UNIT	PAPER NUMBER
Mail Code 089			2877	
Franklin Lakes, NJ 07417-1880			DATE MAILED: 11/05/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	m				
•	1		I AC D				
Office Action Summary	10/047,985		ACHUR, NICHOLAS R.				
	Examiner	Art Unit					
The MAILING DATE of this communication app	Gordon J Stock	2877	ldr ss				
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a repl - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute - Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).  Status	136(a). In no event, however, may a ly within the statutory minimum of th will apply and will expire SIX (6) MC e, cause the application to become	a reply be timely filed hirty (30) days will be considered timel DNTHS from the mailing date of this cand ABANDONED (35 U.S.C. § 133).	y. ommunication.				
Responsive to communication(s) filed on							
· - · · · · · · · · · · · · · · · · · ·	— · nis action is non-final.						
3) Since this application is in condition for allow		atters, prosecution as to th	ne merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims  4)   Claim(s) 1-24 is/are pending in the application	n						
4a) Of the above claim(s) is/are withdra							
5) Claim(s) is/are allowed.	wit from consideration.						
6)⊠ Claim(s) <u>1-24</u> is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/o	or election requirement.						
Application Papers	<b>,</b> , , , , , , , , , , , , , , , , , ,						
9)⊠ The specification is objected to by the Examine	er.						
10)⊠ The drawing(s) filed on <u>14 June 2002</u> is/are: a	)⊠ accepted or b)⊡ object	ed to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12)☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
<ul><li>3. Copies of the certified copies of the prical application from the International But See the attached detailed Office action for a list</li></ul>	ureau (PCT Rule 17.2(a))	).	Stage				
14) Acknowledgment is made of a claim for domest	tic priority under 35 U.S.C	C. § 119(e) (to a provisiona	l application).				
<ul> <li>a)  The translation of the foreign language pr</li> <li>15)  Acknowledgment is made of a claim for domes</li> </ul>							
Attachment(s)							
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>	5) Notice	w Summary (PTO-413) Paper No of Informal Patent Application (PT					
S. Patent and Trademark Office							

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#### **DETAILED ACTION**

### Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the lack of antecedent basis in claim 8: "the group consisting of blood and urine;" in claim 9: "polymer, glass, or crystalline bead."

#### Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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4. Claims 1-4, 7, 10, 11-13, 16-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Hammond et al. (6,195,443).

As for claim 1, Hammond in a system using on-line liquid characterization apparatus discloses the following: a flow cell through which a specimen containing particles to be analyzed is caused to flow (Fig. 1; col. 2, lines 45-65); particles may be magnetic (col. 7, lines 40-45); an illumination source for illuminating an image capturing zone (col. 4, lines 1-5); an imaging optic from the example, a long distance zoom microscope (col. 8, lines 30-40); image capturing means for capturing a still image (col. 3, lines 62-67); image processing means (col. 4, lines 30-40); wherein images of the particles flowing through the flow cell are captured by the image capturing means and analyzed (col. 4, col. 5, lines 1-15).

As for claim 2, the illumination source is brightfield (Fig. 1).

As for claim 3, the image capturing means is a digital camera (col. 3, lines 62-67).

As for claim 4, the flow cell is transparent (col. 4, lines 1-2).

As for claim 7, there is no sheath fluid (Fig. 1, col. 2, lines 50-65; col. 3, lines 1-60).

As for claim 10, a microscope may be used (col. 8, lines 30-40).

As for claim 11, Hammond discloses the following: introducing a specimen that may contain magnetic particles (col. 7, lines 40-45) into an inlet port of a flow cell and moving the specimen from the inlet port to an imaging chamber of the flow cell (Fig. 1, col. 2, lines 45-65; col. 3, lines 1-60); interrogating at least one field of view of the chamber and generating a still image for the at least one field of view and generating a response file for the at least one field of view (col. 3, lines 60-65; col. 4, col. 5, lines 1-15, col. 9, lines 1-20).

As for claim 12, successive fields are done with scanning (col. 6, lines 44-55).

As for claim 13, the specimen flows without a sheath fluid (Fig. 1, col. 2, lines 50-65; col. 3, lines 1-60)

As for claim 16, illumination of the transparent section is performed (col. 4, lines 1-12).

As for claim 17, brightfield light source is provided (Fig. 1).

As for claim 18, a digital camera may be used for still imaging (col. 3, lines 62-67).

As for claim 19, a specimen is coated prior to introduction (col. 7, lines 40-60).

## Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. (6,195,443).

As for claim 20, Hammond discloses everything as above see claim 11. He is silent concerning cells. However, he discloses a fermentation broth (col. 7, lines 42-44). It is well known in the art that fermentation requires yeast cells. Therefore, it would be obvious to one skilled in the art at the time the invention was made that the specimen comprised cells for the sample could be a fermentation broth.

7. Claims 1-6, 8-12, 14-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt (6,251,615).

As to claims 1 and 11, Oberhardt discloses a flow cell through which a specimen containing particles to be analyzed is caused to flow; an illumination source for illuminating an image capturing zone; an imaging optic; image capturing means; image processing means; wherein images are captured of particles flowing and captured in the flow cell within a capture cartridge by image capturing means and are analyzed. And a method is disclosed comprising: introducing a specimen containing particles of interest into an inlet port of a flow cell; moving the specimen from the inlet port to an imaging chamber of the flow cell; interrogating at least one field of view; and creating response files (col. 3, lines 55-67; col. 4; lines 1-50; Fig. 12: cols. 25-26; Fig. 1: col. 12, lines 10-40; col. 13, lines 48-67; col. 14, lines 25-45; Fig. 9b: col. 20, lines 45-67). (The embodiment relied upon is Fig. 12 in view of Fig. 1 for the flow of cells through the capture cartridge and in view of Fig. 9b for the structure of the capture cartridge.) As for producing still images, Oberhardt suggests this by stating that the camera captures signals of the individual cells (col. 27; lines 15-20). In addition, it is well known in the art that cameras take images in frames per second; whereas, a frame is one still image. Therefore, it would be obvious to one skilled in the art that still images are taken for a camera is used to capture the image.

As for claims 2 and 17, Oberhardt demonstrates a brightfield light source (Fig. 12).

As for claims 3 and 18, Oberhardt discloses a digital camera (col. 25, line 18).

As for claim 4, Oberhardt discloses the transparency of the flow cell (Fig. 12).

As for **claim 5**, Oberhardt discloses the flow cell comprising: an inlet port, an imaging chamber, an absorbent pad, a first channel connecting the inlet port to the imaging chamber and a second channel connecting the imaging chamber to the absorbent pad (Fig. 9b; col. 20, lines 45-67; col. 12, lines 10-45; col. 13, lines 48-67).

As for claim 6, Oberhardt discloses an incident light source (col. 25, lines 40-50).

As for claims 8, 20, and 24, Oberhardt discloses blood cells (col. 8, lines 54-65).

As for claim 9, Oberhardt discloses latex beads (col. 15, lines 60-67).

As for claim 10, Oberhardt discloses a microscope (Fig. 12, 70a).

As for claims 12 and 16, Oberhardt discloses successive fields of view thereby at least one field of view is illuminated (col. 26, lines 49-60).

As for claims 14-15, Oberhardt discloses injecting the sample into the inlet port using a syringe and moving step is by syringe (col. 12, lines 15-30).

As for claim 19, Oberhardt discloses staining the particles prior to introduction (col. 26, lines 30-40).

As for claims 21-23, Oberhardt discloses counting the particles; determining the DNA content of the particles; classifying the particles (col. 4, lines 40-50).

#### Conclusion

- 8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:
  - U.S. Patent 4,476,231 to Deindoerfer et al.
  - U.S. Patent 4,519,087 to Deindoerfer
  - U.S. Patent 4,612,614 to Deindoerfer et al.
  - U.S. Patent 5,247,339 to Ogino
  - U.S. Patent 5,449,622 to Yabe et al.

## Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

- 1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the fax cover sheet; and
  - 2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: (703) 872-9306

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (703) 305-4787. The examiner can normally be reached on Monday-Friday, 10:00 a.m. - 6:30 p.m.

Any inquiry of a general nature or relating to the status of this application or proceeding should

be directed to the receptionist whose telephone number is (703) 308-0956.

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October 31, 2003